

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ROANOKE DIVISION**

SHIRE LLC,

Plaintiff,

v.

TRAVIS C. MICKLE, PH.D.,

and

KEMPHARM, INC.,

Defendants.

Civil Action No. 7:10-CV-00434

**MEMORANDUM IN SUPPORT OF SHIRE LLC’S EMERGENCY MOTION TO
PRESERVE EVIDENCE AND CONDUCT FORENSIC EXAMINATION**

Plaintiff Shire LLC (“Shire”), by counsel, submits this brief in support of its Emergency Motion to Preserve Evidence and Conduct Forensic Examination.

I. INTRODUCTION

Shire alleges that Travis C. Mickle, Ph.D. (“Dr. Mickle”) took confidential information and property from his former employer, New River Pharmaceuticals, Inc. (“NRP”), and used these materials for the benefit of himself and the company that he founded, KemPharm, Inc. (“KemPharm”). The discovery process has confirmed these allegations.

Evidence of Defendants’ known misappropriations, however, has not turned up where it would be expected, namely in Defendants’ production of stand-alone electronic documents. And in fact, Shire recently learned that one key computer was not searched at all.

The inconsistencies of Defendants’ document production and electronic search process logically leads to two conclusions: (1) Defendants have deleted evidence concerning their

misappropriation of NRP property; and/or (2) the search protocol for stand-alone electronic documents that Defendants proposed has proven to be deficient, missing documents at the very heart of Shire's claims.

Shire thus has serious concerns that critical evidence has been either destroyed or overlooked by Defendants. With discovery coming to a close on November 21, 2011, Shire seeks immediate access to forensically image and search Defendants' computers, hard drives, storage media, and other devices. Shire believes that only this emergency relief will protect its right to fully discover evidence of Defendants' wrongful conduct.

II. BACKGROUND

A. Dr. Mickle Directed NRP's Drug Discovery Efforts

Dr. Mickle was hired as a Senior Scientist for NRP in 2001. (Compl., ¶ 17 Dkt. No. 1.) He became Director of Drug Discovery and Chemical Development in January 2003, and held that title until his abrupt departure from NRP on October 12, 2005. (*Id.*, ¶¶ 22, 30, 40-41.)

Through his employment, Dr. Mickle was exposed to NRP's drug development know-how and had access to NRP's proprietary information, including without limitation its past, current, and planned research and development activities. (*Id.*, ¶¶ 20-26.) Dr. Mickle also gained access to highly confidential and commercially valuable information about what types of drugs should be pursued, as well as NRP's business plans and strategies. (*Id.*, ¶¶ 25-26.)

B. Shire's Allegations Against Dr. Mickle and KemPharm

Shire's Complaint alleges, in part, that Dr. Mickle has taken and used its confidential information and property for the benefit of himself and KemPharm, in violation of the Employment Agreement and Settlement Agreement that Mickle entered into with NRP, Shire's predecessor. (*See, e.g., id.* ¶¶ 2, 62-64, 66, 69-70, 75, 106-113, 125-132.) Shire also alleges, in

part, that KemPharm tortiously interfered with these contracts, inducing their breach.¹ (*See id.*, ¶¶ 114-124.)

Illustrative of Defendants' wrongful conduct, Shire alleged that:

Attempting to leverage and utilize the NRP Property, KemPharm, under Mickle's direction, has focused its efforts on the very same APIs that the Mickles and the NRP Scientists identified while employed at NRP. Moreover, Mickle has sought to couple these APIs to the very same ligand, amino acids, as did NRP while the Mickles and the NRP Scientists worked for NRP.

(*Id.*, ¶ 63.) The most prominent example of the above is KemPharm's development of its lead compound KP106, which is composed of an amphetamine conjugated to an amino acid. (*See id.*, ¶ 64.) Likewise, NRP104—which was the developmental name for Shire's Vyvanse® product used to treat ADHD—consists of an amphetamine conjugated to an amino acid. (*Id.*, ¶ 14(a).)

C. Dr. Mickle Avers that He Has Not Taken or Used any NRP Confidential Information or NRP Property

On November 9, 2005, Dr. Mickle executed a Declaration pursuant to 28 U.S.C. § 1746 representing and warranting, under penalty of law, that he had returned (or destroyed) all NRP documents containing confidential information, trade secrets, or discoveries; that he did not possess or have control over any NRP property; and that he had reviewed the files and data stored on his computers and that they did not contain confidential information, trade secrets, or discoveries of NRP, or other electronic or digital files or records containing the same. (**Exhibit A**, ¶¶ 2-4.)

¹ Shire also alleges that Dr. Mickle has breached five patent Assignment Agreements and that KemPharm has tortiously interfered with these agreements.

In the course of this litigation, Dr. Mickle also unequivocally stated that he “returned or deleted all New River information in my possession after my departure, except for my submitted paper which I had permission to keep.” (**Exhibit B** at 19.)

D. Discovery Protocol for Electronically Stored Information

As part of the discovery process, the parties exchanged a series of proposals for conducting searches of Electronically Stored Information (“ESI”). Shire proposed that all ESI be captured and produced, subject to Rule 26(b), and that keyword searching techniques be applied to the collected data to identify relevant and responsive material. (*See* Dkt. No. 88-1 at 2-3.) Shire took this position because it believes that keyword searching for all ESI is a valuable tool for identifying responsive documents.

Defendants refused to agree to keyword searching for all ESI, instead proposing that keyword searches only be used for e-mail. (*See id.* at 3-5.) For non-email ESI (*i.e.*, stand-alone electronic documents), Defendants proposed that the parties limit the areas and electronic “folders” to be searched to those that a custodian identified as part of a reasonable, good faith search. (*See id.*) This method, of course, relies on the custodian accurately identifying all of their potentially responsive documents for review.

Defendants’ position was ultimately adopted by Judge Urbanski, and incorporated into the parties’ Supplemental Discovery Plan per his order. (*See* Dkt. Nos. 91, 118.)

E. Defendants’ Misappropriations and the Failure of Evidence to Appear in Defendants’ Production of Stand-Alone Electronic Documents

1. NRP’s Highly Confidential HPLC Methods

While an NRP employee, on March 10, 2005, Dr. Mickle transmitted the seventh chapter of a document entitled “New River Pharmaceuticals, Inc. – Investigational New Drug for NRP104” to another NRP employee via e-mail. (**Exhibit C**). This document relates to NRP’s

proprietary and confidential Investigational New Drug information on NRP104, including a method for determining the purities and impurities in NRP104 by a technique known as high performance liquid chromatography (“HPLC”). In light of Dr. Mickle’s e-mail, his possession of NRP’s highly confidential HPLC method in March 2005, while an NRP employee, cannot be questioned.

The record shows that Dr. Mickle also maintained possession of this highly confidential HPLC method after departing NRP, and used it for the benefit of KemPharm. Portions of it were reproduced in KemPharm’s own documents. (*Compare* Ex. C at NRP0055798-99 with **Exhibit D**.) Metadata embedded in this document confirms that this information came from Dr. Mickle. The document has an “Author” entry of “Travis Mickle” and a “Date Modified” entry of November 17, 2006.

As further evidence of Dr. Mickle’s misappropriation, portions of the same highly confidential NRP HPLC method appear in a second document dated November 17, 2006 that was produced by KemPharm. (*Compare* Ex. C at NRP0055798-99 with **Exhibit E** at KPI0056063.) Portions also appear in a third KemPharm document dated December 10, 2006. (*Compare* Ex. C at NRP0055798-99 with **Exhibit F** at KPI0056269.)

Exhibit F is a letter to Dr. Mickle from a vendor, Cambrex North Brunswick, Inc. This letter indicates that Dr. Mickle not only maintained, but also relayed the highly confidential NRP HPLC method to a third-party, which then included the information in a proposal to KemPharm. In fact, Dr. Mark TePaske of Cambrex confirmed during his deposition on October 20, 2011 that the HPLC method information contained in the Cambrex document was sent to Cambrex from KemPharm:

Q. Did Cambrex -- did Cambrex write any of that HPLC method?

A. There are numerous documents that actually call out these -- these analytical conditions as being used for the analysis of samples during the course of some of the development work.

Q. Where did that information come from?

A. The -- actually from KemPharm.

Q. So the HPLC details here are coming from KemPharm?

A. Yeah.

(See TePaske Dep. Tr. at 117, attached as **Exhibit G**.)

Although the above facts show that Defendants have wrongly used the highly confidential NRP HPLC method, Shire had to deduce this from a comparison of NRP documents and documents that KemPharm produced as its own, as illustrated above. To be clear, Defendants have not produced the underlying NRP document containing the confidential HPLC method (Exhibit C), despite the clear evidence that Defendants have used it.

2. NRP's Highly Confidential Dog Studies

On August 25, 2008, Dr. Mickle sent an email to Christal Mickle attaching a copy of a dog study entitled "Single Dose Intravenous Pharmacokinetic and Oral Bioavailability of NRP104 and Active Metabolite in Dogs." (**Exhibit H**.) As is clear on its face, this dog study was conducted by NRP in 2004. There is no justification for it being in Dr. Mickle's possession after his departure from NRP in October 2005.²

Further, the Summary, Study Objective, and Methods and Experimental Design sections of the dog study were copied verbatim into a KemPharm report, except that NRP104 was replaced with KP106. (*Compare* Ex. H at KPI0191359-61, KPI019135963 *with* **Exhibit I**.) Thus, it is clear that NRP's highly confidential pre-clinical dog protocol for evaluating the

² Page 5 of the dog study (Ex. H. at KPI0191360) is an unsigned signature page that was only available to Dr. Mickle while he was an NRP employee. Moreover, this confidential dog study was never available in the public domain after Dr. Mickle left NRP.

pharmacokinetic and bioavailability properties of NRP104 was used by KemPharm for evaluating KemPharm's KP106.

Although it was produced as part of Defendants' email production (the review of which utilized keyword searching), the 2004 NRP dog study was not produced by Defendants as part of its non-email ESI production as a stand-alone electronic document.

3. NRP's Highly Confidential Albany Molecular Research Report that Identified a Select List of Enzymes for Hydrolysing NRP104

In May of 2005, NRP requested that Albany Molecular Research, Inc. develop and provide a list of a wide range of commercially available hydrolytic enzymes to identify biocatalysts capable of hydrolyzing NRP104. (**Exhibit J.**)

On August 31, 2005, Dr. Mickle was copied on an email from Mark Sawicki of Albany Molecular Research that contained a report with a confidential select list of enzymes for hydrolysis of NRP104 and other information (hereinafter referred to as "the Albany Molecular Research report"). (**Exhibit K.**) On September 7, 2005 (shortly before his departure from NRP), Dr. Mickle emailed this report to his personal email account at 4:50 PM, and again at 9:51 PM. (Ex. K at NRP0029904, **Exhibit L** at NRP0052763.)

There is no evidence that shows Dr. Mickle ever returned the Albany Molecular Research report to NRP, and this report was not produced by Defendants during discovery. Dr. Mickle admits e-mailing the report to himself, but states that he "believe[s]" that he deleted the Albany Molecular Research report from his home computer prior to his departure from NRP. (Ex. B at 19.) In light of Dr. Mickle's demonstrably false statements generally disavowing his use of NRP's confidential information and property (*see* Ex. A; Ex. B at 19), there are serious doubts about the accuracy of this "belief," particularly the timing of the claimed deletion.

F. Shire Discussed the Misappropriations with Defendants and Its Concerns About the Destruction of Evidence and/or the Deficiencies in Defendants' Search for Non-Email ESI

After piecing together the above instances of Dr. Mickle's misappropriation of NRP's highly confidential information and property, Shire wrote to defense counsel on October 21, 2011. Shire sought immediate access to forensically image Defendants' twenty-one devices comprising computers and storage media identified in their responses to Shire's interrogatories, and reminded Defendants of the duty to preserve evidence. (*See Exhibit M; Exhibit N, Responses to Interrogatory Nos. 5 and 6.*) That same day, Shire also served upon Defendants a Request for Entry Upon Land for Inspection. (**Exhibit O.**) On October 27, 2011, counsel for the parties conducted a telephonic meet and confer during which Defendants refused to permit such an inspection.

During this meet and confer, Defendants also had no explanation for why the NRP HPLC method, the NRP dog study, and the NRP commissioned Albany Molecular Report were not part of Defendants' non-email ESI production as stand-alone electronic documents.

G. Shire Learns that Defendants Did Not Search a Key Laptop Computer During Discovery

During the October 27, 2011 meet and confer, Shire also learned that Defendants failed to search an IBM Type 2652 Thinkpad Laptop with Serial Number 78-KPTDY (the "IBM laptop") that was identified in response to Shire's interrogatories. (*See Ex. N, Response to Interrogatory No. 6.*) The IBM laptop was used by Dr. Mickle's wife, Christal Mickle, from 2002 until 2008-09. (*Id.*) Christal Mickle formerly worked at NRP, and is presently an officer at KemPharm. (Compl., ¶¶ 27, 53.) Use of this laptop thus spans Dr. Mickle's transition from NRP to KemPharm, a critical time period for this case.

The IBM laptop was identified with a notation of “[f]ails to boot.” (Ex. N, Response to Interrogatory No. 6.) Shire, however, rightfully expected that the hard drive of this computer would still have been searched under the Supplemental Discovery Plan. Defendants also failed to inform Shire that the IBM laptop was not searched; Shire only learned this when specifically asking defense counsel during the October 27, 2011 telephonic meet and confer.

III. SUMMARY OF RELEVANT LAW

Courts have routinely granted access to forensically image computer hard drives and other devices in cases involving electronic documents. For example, recognizing that “[e]lectronic evidence can easily be erased and manipulated,” a party seeking forensic examination of computers was granted expedited discovery to “enter the sites where the computers . . . are located in order to obtain a ‘mirror image’ of the computer equipment containing electronic data . . . with the assistance of a computer forensic expert.” *Physicians Interactive v. Lathian Sys. Inc.*, No. 03-1193, 2003 U.S. Dist. LEXIS 22868, at *30 (E.D. Va. Dec. 5, 2003).

Other courts have also recognized that “mirror imaging” is appropriate where computer content is connected to the basis of the lawsuit:

It is not unusual for a court to enter an order requiring the mirror imaging of the hard drives of any computers that contain documents responsive to an opposing party’s request for production of documents. *See e.g., Communications Center, Inc. v. Hewitt*, 2005 U.S. Dist. LEXIS 10891, 2005 WL 3277983 at *1 (E.D. Cal., Apr. 5, 2005). A “mirror image” is generally described as “a forensic duplicate, which replicates bit for bit, sector for sector, all allocated and unallocated space, including slack space, on a computer hard drive.” *Id.* Thus, in similar cases where trade secrets and electronic evidence are both involved, the Courts have granted permission to obtain mirror images of the computer equipment which may contain electronic data related to the alleged violation. *See e.g., Physicians Interactive v. Lathian Systems, Inc.*, 2003 U.S. Dist. LEXIS 22868, 2003 WL 23018270 at *10 (E.D.Va., Dec. 5, 2003); *Antioch Co. v. Scrapbook Borders, Inc.*,

210 F.R.D. 645, 651-53 (D. Minn. 2002). This is one method of assuring the preservation of evidence since electronic evidence can easily be erased and manipulated, either intentionally or unintentionally (by overwriting through continued use of the computer).

Balboa Threadworks, Inc. v. Stucky, No. 05-1157, 2006 U.S. Dist. LEXIS 29265, at *7–8 (D. Kan. Mar. 24, 2006).

Discrepancies or inconsistencies in the responding party's discovery responses may further justify a party's request to allow an expert to create and examine a mirror image of a hard drive. See *Ameriwood Indus. v. Liberman*, No. 4:06-cv-524, 2006 U.S. Dist. LEXIS 93380, at *13 (E.D. Mo. Dec. 27, 2006) (citation omitted).

The Supplemental Discovery Plan entered in this case states that “[i]nformation that a party in good faith identifies as not reasonably accessible may be produced upon agreement of the parties to share the cost associated with such production.” (Dk. 118 at 2.) This language tracks closely with the Federal Rules of Civil Procedure, which set forth the following burden-shifting analysis a court should implement in deciding whether to compel production of ESI:

On motion to compel discovery . . . , the party from whom discovery is sought must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

Fed. R. Civ. P. 26(b)(2)(B).

Finally, Shire notes that this Court has “wide latitude in controlling discovery.” *Rowland v. Am. Gen. Fin., Inc.*, 340 F.3d 187, 195 (4th Cir. 2003) (quoting *Ardrey v. United Parcel Serv.*, 798 F.2d 679, 682 (4th Cir. 1986)).

IV. ARGUMENT

Something is amiss in Defendants' document productions. It is clear that Defendants have used certain specific pieces of NRP's confidential information and property, but these were not included as part of their non-email ESI production. The only reasonable conclusions to draw are that (1) Defendants have deleted NRP's documents in an effort to conceal their wrongful conduct, despite assurances to the contrary, and/or (2) the search protocol suggested by Defendants for non-email ESI—which prohibited keyword searching—is fatally defective.

While Shire has still been able to concretely identify instances of misappropriation, it is justifiably concerned that evidence of other, and perhaps widespread, copying and use of NRP's confidential information and property has been missed or intentionally suppressed. Adding to Shire's concerns is the recent discovery that one critical computer that was identified by Defendants—the IBM laptop—was nevertheless not searched. Further concrete evidence of Defendants' wrongful acts would most likely be found in ESI, given that it contains unique identifiers such as metadata, filenames, document sources, and date information that can easily be searched.

Given the facts detailed above, and the fact that discovery closes on November 21, 2011, Shire should be awarded emergency relief to conduct forensic imaging and examination.

A. Defendants Should be Compelled to Preserve Evidence and Grant Immediate Access to Forensically Image Computer Hard Drives and Other Devices

Shire's requests for forensic examination are based on much more than mere speculation; the record shows that Defendants have misappropriated specific NRP documents. The record also shows that the full evidence of these particular instances of misappropriation has not been produced. The full magnitude of Defendants' misappropriations remains unknown. In light of

this history, the most efficient and effective method to address this problem is to conduct a computerized forensic examination.

Accordingly, Shire requests that the Court order a forensic examination of all computers, hard drives, storage media, and other devices identified in Defendants' interrogatory responses (*see* Ex. N, Responses to Interrogatory Nos. 5 and 6) as well as any other devices used by Defendants that may contain information relating to the present litigation (collectively referred to herein as the "Devices"). Such a forensic examination will freeze and capture a record of all electronic evidence, so that it cannot be further erased, manipulated, and overwritten. It will facilitate a targeted search to capture all improper uses of NRP information. It also is the only way to locate evidence of NRP documents that Defendants may have deleted, by searching the Devices' hard drives using forensic software.

B. Shire Has Retained Forensic Examination Expert Peter Garza to Image and Search Defendants' Devices in a Manner that Prevents Shire from Having Access to the Search Results Until Permission Is Granted

To assist in forensic examination, Shire has retained Peter Garza of Data Forté Corporation (www.dataforte.com), a respected expert in the fields of computer forensics and electronic discovery. Mr. Garza's curriculum vitae is attached for this Court's review, as is an executed declaration, and executed declaration to the Stipulated Protective Order. (**Exs. P, Q and R.** *See also* Dkt. No. 127.)

As part of the data collection process, Shire requests that this Court grant Data Forté access to create an image, e.g., exact copy, of the storage mechanism(s) of each Device. Data Forté will retain a copy of each image and also provide counsel for Defendants with copies. At no time will Shire or its attorneys have possession of these "raw" images. (**Exhibit R, ¶ 9.**)

Shire also requests that this Court grant Data Forté access to conduct forensic examination of the images, including the use of keyword searching, metadata searching,

document comparisons (between NRP documents and Defendants' documents) and other searching techniques as Data Forté may find necessary, to locate and collect targeted and relevant information. (*Id.*, ¶ 10.) This forensic examination should include at least files currently stored on each Device as well as files that have been deleted. (*Id.*)

At the conclusion of the data collection process, Data Forté will provide counsel for Defendants with lists of relevant documents, may then be reviewed for privilege. (*Id.*, ¶ 11.) Due to the compressed window for completing discovery in this case, Shire requests that this Court allow Data Forté to release documents to Shire 48 hours after providing Defendants a list of relevant documents, *i.e.*, if Defendants fail to claim privilege on any document within 48 hours, any claim to privilege will be waived.

Documents that are not deemed privileged will then be distributed to Shire by Data Forté, and Bates-stamped with a "DF" prefix. (*Id.*) Data Forté will also provide a copy of all Bates-stamped documents to Defendants. All DF documents will presumptively be marked and treated as Highly Confidential under the parties' Stipulated Protective Order.

This forensic examination will be conducted in a manner that imposes minimal burden on Defendants. Shire will cover one hundred percent (100%) of the cost of forensic examination conducted by Peter Garza and Data Forté.

C. Documents on the Unsearched IBM Laptop Are Easily Accessible

Defendants have indicated that the unsearched IBM laptop presently will not boot. Booting a computer is not required to search data on its hard drive, which stores data independent of other computer hardware, functionality, and/or resources. (Ex. R, ¶ 5.) Defendants should have secured the appropriate technical resources to boot the laptop and/or remove the hard drive for the purposes of searching the easily-recoverable information stored therein. (*Id.*)

As part of the forensic examination, Shire is willing to cover one hundred percent (100%) of the cost of booting the laptop and/or removing the hard drive for searching, which is expected to take an entry-level technical support professional less than two hours. (*Id.*, ¶ 6.)

Shire also points out that the Supplemental Discovery Plan states that “[i]nformation that a party in good faith identifies as not reasonably accessible may be produced upon agreement of the parties to share the cost associated with such production.” Moreover, courts have applied the “good cause” exception in Rule 26(b)(2)(B) in finding cause to require restoration of “inaccessible” ESI, even at the cost of millions of dollars, due to a plaintiff’s specific explanation of why requested data was relevant to a case. *See, e.g., Takeda Pharm. Co. v. Teva Pharm. USA, Inc.*, No. 09-841-SLR-LPS, 2010 WL 2640492, at *1 (D. Del. June 21, 2010).

Here, at least four factors justify and warrant forensic examination of the IBM laptop. First, Defendants failed to search the IBM laptop or notify counsel of such a failure. Second, the IBM laptop is one of the few devices identified by Defendants to have been in service at the time of Dr. Mickle’s transition from NRP to KemPharm, a critical time period in this case. Third, the hard drive on the laptop is easily accessible. Finally, Shire has agreed to cover the cost of accessing and forensically examining the laptop.

V. CONCLUSION

For the reasons set forth above, Shire requests that the Court order that: (1) Defendants preserve evidence on all computers, hard drives, storage media, and other devices, including the unsearched IBM laptop; and (2) that Peter Garza of Data Forté Corporation, an expert in the fields of computer forensics and electronic discovery, be granted immediate access to forensically image and examine these computers, hard drives, storage media, and other devices, on the terms and conditions specified herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of October, 2011, a true and correct copy of the foregoing was filed with the Clerk of Court using the CM/ECF system, which provided electronic service to all counsel of record.

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